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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,682	02/10/2004	Rodolfo A. Morales	578492000510	3785

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MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER
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RYCKMAN, MELISSA K

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3773

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10/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,682	<b>Applicant(s)</b> MORALES ET AL.	
	<b>Examiner</b> MELISSA RYCKMAN	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-41 and 43-58 is/are pending in the application.
- 4a) Of the above claim(s) 49-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-41 and 43-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/16/10</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to amendments filed 8/16/10.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the clip being T-shaped (as supported in paragraph 93 in the current specification) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-40 and 44-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Brock (U.S. Pub. No. 2002/0087169).

Claim 37: Brock teaches a device for applying at least one clip to annular tissue of a heart valve (Fig. 32) the device comprising; a shaft having a proximal end and a distal end (342, Fig. 31); and at least one actuator (para. 262) at or near the proximal end of the shaft for causing the device to advance the tethered clip assembly from the shaft (Fig. 31, para. 262), wherein the tethered clip assembly has a first deployed configuration (Fig. 31) and a second deployed configuration (Fig. 32), the tethered clip assembly in the first deployed configuration (Fig. 32) comprising at least two clips wherein the clips each comprise two tissue- piercing legs (Fig. 31, 351, para. 262) joined by a loop, are separated by a first distance and coupled to a tether (312) that passes through the loops transversely to the legs, and wherein when the tethered clip assembly is in its second deployed configuration (Fig. 33) the tether is under longitudinal tension (para. 263) and the first distance is reduced to a second distance

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(para. 263 and 273), and wherein the at least two clips are in a closed tissue-piercing position and at least one clip is slidable on the tether (sliding motion between the tether and clip) when the tethered clip assembly is in both its first and second deployed configuration.

Claims 38-40: Brock teaches the device further comprises a clip crimping member (distal portion of 352, Fig. 31), a plurality of clips (Fig. 31), each plurality of clips is couple to the tether (312).

Claim 44: Brock teaches a system for applying at least one clip to annular tissue of a heart valve, comprising: the device as claimed above in claim 37; and a stabilization device (334, Fig. 32) to capture and immobilize the annular tissue relative to the remainder of the heart (265).

Claims 45-47: Brock teaches a visualization device capable of providing direct visualization to the annular tissue (para. 272), including an ultrasonic imaging transducer and an optical viewing element disposed within a transparent element (para. 115).

Claim 48: Brock teaches an inflatable balloon with transparent medium (para. 265).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brock (U.S. Pub. No. 2002/0087169) as applied to claim 37 above, and further in view of Friedman (WO 02/053011 A2).

Brock teaches the claimed invention, however is silent regarding the clip being T-shaped. However, Friedman teaches a clip with a loop, and the clip is T-shaped (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to alter the shape of the clip of Brock to the shape of Friedman, as this is appropriate for certain types of tissue and for securely anchoring the clip for the tissue.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brock (U.S. Pub. No. 2002/0087169) as applied to claim 40 above, and further in view of Yoon (U.S. Patent No. 5984933).

Brock teaches the claimed invention however, only specifies one loop on each clip and one tether connecting the clips, however Yoon teaches each of the plurality of clips includes two eyelets (2228), and two tethers (2218a and 2218) has parallel segments passing through both eyelets of each clip (Fig. 44). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use two tether, and two loops to accommodate the tethers as this aids in correct placement of the clips in the tissue of the heart valve.

### ***Double Patenting***

The examiner acknowledges the receipt of the terminal disclaimer regarding U.S. Patent No. 6,986,775, however at this time the office has neither approved or denied the disclaimer, so the rejection will be maintained until it is resolved. At this time it is not necessary for the applicant to send another terminal disclaimer.

Claims 37-41 and 43-48 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,986,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because '775 teaches all elements of the current application.

Claims 37-41 and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-100 of copending Application No. 11/237,461. Although the conflicting claims are not identical, they are not patentably distinct from each other because all elements of the current application are claimed in application '461.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 37-46 of copending Application No. 12/131,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because all elements of the current application are claimed in application '840.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 37-41 and 43-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58-94 of copending Application No. 12/132,375. Although the conflicting claims are not identical, they are not patentably distinct from each other because all elements of the current application are claimed in application '375.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on a flexible schedule, email address is melissa.ryckman@uspto.gov.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MKR

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